IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
Abingdon Division

RICKY L. RASH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 1:08cv15**
	)	
STRYKER CORPORATION,	)	
STRYKER SALES CORPORATION,	)	
and STRYKER INSTRUMENTS,	)	
	)	
Defendants.	)	

DEFENDANTS' ANSWER AND AFFIRMATIVE DEFENSES

Defendants Stryker Corporation, Stryker Sales Corporation, and Stryker Instruments (collectively "Defendants"), by counsel, state as follows for their response to Plaintiff's Complaint:

ANSWER

For their answer to Plaintiff's Complaint, Defendants state as follows:

PARTIES

1. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 1 of the Complaint and therefore deny the same.

2. Defendants admit that Stryker Corporation and Stryker Sales Corporation are corporations organized under the laws of the State of Michigan, with their principal place of business located in Kalamazoo, Michigan. The allegation that Stryker Corporation and Stryker Sales Corporation are residents and citizens of Michigan is a legal conclusion to which no

response is required. Except as expressly admitted herein, the allegations in Paragraph 2 of the Complaint are denied.

3. Defendants admit that Stryker Instruments is a division of Stryker Corporation, with its principal place of business in Kalamazoo, Michigan. The allegation that Stryker Instruments is a resident and citizen of Michigan is a legal conclusion to which no response is required. Except as expressly admitted herein, the allegations in Paragraph 3 of the Complaint are denied.

4. With respect to the allegations in Paragraph 4 of the Complaint, Defendants admit that Stryker Corporation designed, manufactured, tested, marketed, and labeled a product called a "pain pump." Defendants admit that Stryker Sales Corporation sold a product called a "pain pump." Except as expressly admitted herein, the allegations in Paragraph 4 of the Complaint are denied.

JURISDICTION AND VENUE

5. The allegations contained in Paragraph 5 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5 of the Complaint, but concede the Court's subject matter jurisdiction.

6. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 6 of the Plaintiff's Complaint and therefore deny the same.

7. The allegations contained in Paragraph 7 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, Defendants admit that Stryker Sales Corporation conducts business in Virginia, and deny that Stryker

Corporation conducts business in Virginia. Except as expressly admitted herein, the allegations in Paragraph 7 of the Complaint are denied.

BACKGROUND

8. With respect to the allegations contained in Paragraph 8 of the Complaint, Defendants deny that any product of, or wrongful conduct by, Defendants caused or contributed in any manner to any damage or injury allegedly suffered by Ricky L. Rash. Defendants admit that Stryker Corporation designed, manufactured, tested, marketed, and labeled a product called a "pain pump," and that Stryker Sales Corporation sold a product called a "pain pump." The nature of the action speaks for itself, and to the extent a response is required to the remaining allegations contained in Paragraph 8 of the Complaint, those allegations are denied.

9. With respect to the allegations in Paragraph 9 of the Complaint, Defendants admit that Stryker Corporation designed, manufactured, tested, marketed, and labeled a product called a "pain pump," and that Stryker Sales Corporation sold a product called a "pain pump." Except as expressly admitted herein, Defendants deny the allegations contained in Paragraph 9 of the Complaint.

10. In response to the allegations Paragraph 10 of the Complaint, Defendants admit that Stryker Corporation designed, manufactured, tested, marketed, and labeled a product called a "pain pump," and that Stryker Sales Corporation sold a product called a "pain pump." Defendants admit that pain pumps are intended to deliver, via catheter, continuous and rate-controlled amounts of pain medication for post-surgical pain management. Defendants further admit that pain pumps are designed and intended to be used with commonly used local anesthetics as prescribed by physicians. Defendants are without knowledge or information

sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 10 of the Complaint, and therefore deny the same.

11. In response to Paragraph 11 of the Plaintiff's Complaint, Defendants admit that pain pumps are designed and intended to be used with commonly used local anesthetics as prescribed by physicians. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 11 of the Complaint, and therefore deny the same.

12. Defendants deny the allegations contained in Paragraph 12 of the Complaint.

13. Defendants admit that Stryker Corporation designed, manufactured, tested, marketed, and labeled a product called a "pain pump," and that Stryker Sales Corporation sold a product called a "pain pump." Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 13 of the Complaint, and therefore deny the same.

14. With respect to the allegations in Paragraph 14 of the Complaint, Defendants expressly deny that any condition or injury suffered by Mr. Rash was contributed to or caused by any product of, or wrongful conduct by, the Defendants. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 14, and therefore deny the same.

15. With respect to the allegations in Paragraph 15 of the Complaint, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning whether Mr. Rash now requires a full shoulder replacement or the reason therefore, and therefore deny the same. Defendants expressly deny that the need for any such replacement was contributed to or caused by product of, or any wrongful conduct by, the Defendants.

16. In response to the allegations contained in Paragraph 16 of the Complaint, Defendants deny the allegations contained in the first sentence of Paragraph 16. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in the second sentence of Paragraph 16, and therefore deny the same.

COUNT I

NEGLIGENCE

17. In response to Paragraph 17 of the Complaint, Defendants incorporate by reference their responses to Paragraphs 1 through 16, inclusive, of the Complaint as though fully set forth herein.

18. The allegations contained in Paragraph 18 of the Complaint set forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations contained in Paragraph 18 of the Complaint.

19. Defendants deny the allegations contained in Paragraph 19 of the Complaint.

20. Defendants deny the allegations contained in Paragraph 20 of the Complaint.

21. Defendants deny the allegations contained in Paragraph 21 of the Complaint.

22. Defendants deny the allegations contained in Paragraph 22 of the Complaint.

23. Defendants deny the allegations contained in Paragraph 23 of the Complaint.

Defendants deny that Plaintiff is entitled to any of the relief demanded in the unnumbered "wherefore" paragraph following Paragraph 23 of the Complaint.

COUNT II

PRODUCTS LIABILITY / DESIGN DEFECT

24. In response to Paragraph 24 of the Complaint, Defendants incorporate by reference their responses to Paragraphs 1 through 23, inclusive, of the Complaint as though fully set forth herein.

25. In response to the allegations contained in Paragraph 25, Defendants admit that Stryker Corporation designed, manufactured, tested, marketed, and labeled a product called a "pain pump," and that Stryker Sales Corporation sold a product called a "pain pump." Except as expressly admitted herein, Defendants deny the allegations contained in Paragraph 25 of the Complaint.

26. Defendants deny the allegations contained in Paragraph 26 of the Complaint.

27. Defendants deny the allegations contained in Paragraph 27 of the Complaint.

28. Defendants deny the allegations contained in Paragraph 28 of the Complaint.

29. Defendants deny the allegations contained in Paragraph 29 of the Complaint.

30. Defendants deny the allegations contained in Paragraph 30 of the Complaint.

Defendants deny that Plaintiff is entitled to any of the relief demanded in the unnumbered "wherefore" paragraph following Paragraph 30 of the Complaint.

COUNT III

PRODUCTS LIABILITY / DEFECTIVE MANUFACTURING

31. In response to Paragraph 31 of the Complaint, Defendants incorporate by reference their responses to Paragraphs 1 through 30, inclusive, of the Complaint as though fully set forth herein.

32. In response to the allegations contained in Paragraph 32, Defendants admit that Stryker Corporation designed, manufactured, tested, marketed, and labeled a product called a "pain pump," and that Stryker Sales Corporation sold a product called a "pain pump." Except as expressly admitted herein, Defendants deny the allegations contained in Paragraph 32 of the Complaint.

33. Defendants deny the allegations contained in Paragraph 33 of the Complaint.

34. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 34 of the Complaint, and therefore deny the same.

35. Defendants deny the allegations contained in Paragraph 35 of the Complaint.

Defendants deny that Plaintiff is entitled to any of the relief demanded in the unnumbered "wherefore" paragraph following Paragraph 35 of the Complaint.

COUNT IV

FAILURE TO WARN

36. In response to Paragraph 36 of the Complaint, Defendants incorporate by reference their responses to Paragraphs 1 through 35, inclusive, of the Complaint as though fully set forth herein.

37. In response to the allegations contained in Paragraph 37, Defendants admit that Stryker Corporation designed, manufactured, tested, marketed, and labeled a product called a "pain pump," and that Stryker Sales Corporation sold a product called a "pain pump." Except as expressly admitted herein, Defendants deny the allegations contained in Paragraph 37 of the Complaint.

38. Defendants deny the allegations contained in Paragraph 38 of the Complaint.

39. Defendants deny the allegations contained in Paragraph 39 of the Complaint.

40. With respect to the allegations contained in Paragraph 40 of the Complaint, Defendants lack knowledge or information sufficient to form a belief as to the status of Mr. Rash's knowledge at the time of his alleged use of a pain pump, and therefore deny the same. Defendants deny the remaining allegations contained in Paragraph 40 of the Complaint.

41. Defendants deny the allegations contained in Paragraph 41 of the Complaint.

42. Defendants deny the allegations contained in Paragraph 42 of the Complaint.

43. Defendants deny the allegations contained in Paragraph 43 of the Complaint.

44. Defendants deny the allegations contained in Paragraph 44 of the Complaint.

Defendants deny that Plaintiff is entitled to any of the relief demanded in the unnumbered "wherefore" paragraph following Paragraph 44 of the Complaint.

COUNT V

FRAUDULENT MISREPRESENTATION

45 – 54. Count V of the Complaint, including Paragraphs 45 through 54, was dismissed by the Court on December 17, 2008 pursuant to Defendants' Rule 12(b)(6) Motion to Dismiss. Accordingly, no response to Paragraphs 45 through 54 of the Complaint is required. To the extent a response is required, Defendants deny the allegations contained in Paragraphs 45 through 54, and further deny that Plaintiff is entitled to any of the relief demanded in the unnumbered "wherefore" paragraph following Paragraph 54 of the Complaint.

COUNT VI

FRAUDULENT CONCEALMENT

55 – 62. Count VI of the Complaint, including Paragraphs 55 through 62, was dismissed by the Court on December 17, 2008 pursuant to Defendants' Rule 12(b)(6) Motion to Dismiss. Accordingly, no response to Paragraphs 55 through 62 of the Complaint is required.

To the extent a response is required, Defendants deny the allegations contained in Paragraphs 55 through 62, and further deny that Plaintiff is entitled to any of the relief demanded in the unnumbered "wherefore" paragraph following Paragraph 62 of the Complaint.

COUNT VII

NEGLIGENT MISREPRESENTATION

63 – 68. Count VII of the Complaint, including Paragraphs 63 through 68, was dismissed by the Court on December 17, 2008 pursuant to Defendants' Rule 12(b)(6) Motion to Dismiss. Accordingly, no response to Paragraphs 63 through 68 of the Complaint is required. To the extent a response is required, Defendants deny the allegations contained in Paragraphs 63 through 68, and further deny that Plaintiff is entitled to any of the relief demanded in the unnumbered "wherefore" paragraph following Paragraph 68 of the Complaint.

COUNT VIII

PRODUCTS LIABILITY – BREACH OF IMPLIED WARANTY

69. In response to Paragraph 69 of the Complaint, Defendants incorporate by reference their responses to Paragraphs 1 through 68, inclusive, of the Complaint as though fully set forth herein.

70. In response to the allegations contained in Paragraph 70, Defendants admit that Stryker Corporation designed, manufactured, tested, marketed, and labeled a device called a "pain pump," and that Stryker Sales Corporation sold a device called a "pain pump." Defendants deny that they had knowledge that any pain pump used by Plaintiff was to be used for any purpose other than its ordinary purpose. Except as expressly admitted herein, the allegations in Paragraph 70 of the Complaint are denied.

71. Defendants deny the allegations contained in Paragraph 71 of the Complaint.

72. Defendants deny the allegations contained in Paragraph 72 of the Complaint.

73. Defendants deny the allegations contained in Paragraph 73 of the Complaint.

Defendants deny that Plaintiff is entitled to any of the relief demanded in the unnumbered "wherefore" paragraph following Paragraph 73 of the Complaint.

COUNT IX

BREACH OF EXPRESS WARRANTY

74 – 82. Count IX of the Complaint, including Paragraphs 74 through 82, was dismissed by the Court on December 17, 2008 pursuant to Defendants' Rule 12(b)(6) Motion to Dismiss. Accordingly, no response to Paragraphs 74 through 82 of the Complaint is required. To the extent a response is required, Defendants deny the allegations contained in Paragraphs 74 through 82, and further deny that Plaintiff is entitled to any of the relief demanded in the unnumbered "wherefore" paragraph following Paragraph 82 of the Complaint.

COUNT X

PRODUCTS LIABLITY
DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS

83 – 87. Count X of the Complaint, including Paragraphs 83 through 87, was dismissed by the Court on December 17, 2008 pursuant to Defendants' Rule 12(b)(6) Motion to Dismiss. Accordingly, no response to Paragraphs 83 through 87 of the Complaint is required. To the extent a response is required, Defendants deny the allegations contained in Paragraphs 83 through 87, and further deny that Plaintiff is entitled to any of the relief demanded in the unnumbered "wherefore" paragraph following Paragraph 87 of the Complaint.

COUNT XI

PRODUCTS LIABILITY
DEFECT DUE TO FAILURE TO ADEQUATELY TEST

88 - 92. Count XI of the Complaint, including Paragraphs 88 through 92, was dismissed by the Court on December 17, 2008 pursuant to Defendants' Rule 12(b)(6) Motion to Dismiss. Accordingly, no response to Paragraphs 88 through 92 of the Complaint is required. To the extent a response is required, Defendants deny the allegations contained in Paragraphs 88 through 92, and further deny that Plaintiff is entitled to any of the relief demanded in the unnumbered "wherefore" paragraph following Paragraph 92 of the Complaint.

COUNT XII

VIOLATION OF VIRGINIA CONSUMER PROTECTION ACT OF 1977
(Va. Code Ann. 59.1-196 et seq.)

92 – 97. Count XII of the Complaint, including Paragraphs 92 through 97, was dismissed by the Court on December 17, 2008 pursuant to Defendants' Rule 12(b)(6) Motion to Dismiss. Accordingly, no response to Paragraphs 92 through 97 of the Complaint is required. To the extent a response is required, Defendants deny the allegations contained in Paragraphs 92 through 97, and further deny that Plaintiff is entitled to any of the relief demanded in the unnumbered "wherefore" paragraph following Paragraph 97 of the Complaint.

AS TO RELIEF REQUESTED

98. Defendants deny each and every allegation in the Prayer for Relief and specifically deny that Plaintiff is entitled to any relief whatsoever.

GENERAL DENIALS

99. Defendants deny each and every allegation of Plaintiff's Complaint not expressly admitted or otherwise pleaded to in this Answer.

100. Defendants deny that they are liable for any conduct, defective product, failure to warn, breach of warranty, or negligence of any kind or nature whatsoever that would warrant the imposition of damages against them, as alleged or at all.

SEPARATE, ALTERNATIVE, AND AFFIRMATIVE DEFENSES

For their separate, alternative, and affirmative defenses, Defendants allege as follows:

1. Plaintiff's Complaint, and each claim contained therein, fails to state a claim against Defendants upon which relief can be granted.

2. The plaintiff waived and is estopped from asserting any claim against Defendants for operative and post-operative complications associated with his May 10, 2006 shoulder surgery and alleged use of a pain pump.

3. Any alleged injuries were the result of the intervening or superceding conduct of the plaintiff, independent third-parties, or events over whom or over which Defendants had no control and no duty to control.

4. The device that is the subject of this Complaint was safe as feasible for a socially desirable purpose.

5. The device that is the subject of this Complaint, including its design and the methods and techniques of manufacturing, inspecting, testing, and distributing it, conformed with the prevailing standards and customs of the state-of-the-art of the industry at all relevant times; and at the time any such device left the control of the Defendants, a practical and technically feasible alternative design was not available that would have prevented the harm for which the plaintiff seeks to recover against Defendants without substantially impairing the usefulness or intended purposes of such device.

6. The alleged injuries described in Plaintiff's Complaint may have been the result of an alteration or modification of the device that is the subject of this Complaint, which was not reasonably foreseeable, was made by a person other than Defendants, and was made subsequent to the time of original sale; and thus, the alteration or modification was the proximate cause of any alleged injuries and damages, thereby precluding liability of Defendants.

7. Any alleged defects in the device that is the subject of this Complaint are inherent characteristics of the device components which cannot be eliminated without substantially compromising the device's usefulness or desirability.

8. The utility of the device that is the subject of this Complaint outweighs any associated risk.

9. Any alleged damages may be limited in whole or part by the plaintiff's failure to mitigate.

10. The proximate cause of the alleged injuries described in Plaintiff's Complaint may have been the use of the device that is the subject of this Complaint for a purpose, in a manner, or in an activity other than that which was reasonably foreseeable or was contrary to an express or adequate warning appearing on, attached to, or delivered with the device.

11. The plaintiff's negligence may have contributed in whole or in part to cause any alleged injuries. Plaintiff's claims may be barred by his contributory negligence or fault.

12. Some or all of the claims against Defendants may fail due to the lack of a duty owed to the plaintiff.

13. Defendants had no duty to provide a warning for the device that is the subject of the Complaint other than the warnings provided in conformity with the requirements of the federal Food, Drug and Cosmetic Act and regulations of the Food and Drug Administration.

14. The device that is the subject of this Complaint was not and never has been defective in design or formulation because it is an ethical, federally-regulated medical device; Defendants provided adequate warnings and instructions to the physician and/or healthcare professional who dispensed the device; and neither the federal Food, Drug and Cosmetic Act nor the federal Food and Drug Administration require that Defendants give any warning or instruction relative to the device directly to the ultimate user of that device.

15. The learned intermediary doctrine precludes Plaintiff's allegations that Defendant owed any duty to warn Plaintiff of any alleged foreseeable risks in the use of Defendants' products.

16. The device that is the subject of this Complaint was a reasonably safe medical device because reasonable instructions or warnings regarding the foreseeable risks of harm were provided to the prescribing physician and/or other healthcare professionals who were in a position to reduce the risks of harm in accordance with those instructions or warnings.

17. Plaintiff, in consenting to the treatment prescribed by a physician or other healthcare professional, expressly and voluntarily assumed the risk of any injury or adverse effects associated with the device that is the subject of this Complaint.

18. Plaintiff's physicians and other medical care providers and their agents, servants and employees were sophisticated users of the subject device and possessed adequate information concerning warnings, precautions and potential complications for those physicians and other medical providers to assess the risks versus the benefits of the subject device before they prescribed it. Therefore, Plaintiff's claims against Defendants are barred.

19. No action or inaction by Defendants was the proximate cause of Plaintiff's injuries, if any.

20. Defendants are not subject to liability pursuant to the applicable provisions of the Restatement (Second) of /Torts and/or Restatement (Third) of Torts: Products Liability.

21. Plaintiff's claims are barred and/or preempted, in whole or in part, by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 *et seq.*, the 1976 Medical Device Amendments thereto, and the Supremacy Clause of Article VI of the United States Constitution.

22. Plaintiff's claims are barred, in whole or in part, because there is no private right of action under the Federal Food, Drug & Cosmetic Act and the Medical Device Amendments thereto.

23. The literature for any product manufactured by the Defendants gave full, complete and adequate warnings as required by applicable federal statutes and regulations. Assuming, arguendo, that Plaintiff's claims are not totally preempted, Defendants' conduct or device cannot give rise to any of the stated causes of action.

24. Plaintiff and his physicians did not rely on any express or implied warranties with respect to the use of the device that is the subject of this Complaint.

25. Plaintiff's alleged injuries were caused by factors other than, and unrelated to, any product or activity of the Defendants, including but not limited to pre-existing medical, genetic, and/or environmental conditions, diseases or illnesses. The Defendants had no control over such factors and such factors were not due to or caused by the fault, lack of care, negligence, breach of warranty, or breach of any duty by the Defendants.

26. Plaintiff's alleged medical care and expenses may not have been reasonably necessary.

27. Some or all of Plaintiff's claims may be barred under the applicable statute of limitations or the doctrine of laches.

28. Defendants reserve the right to amend and add other defenses that become apparent through discovery of the evidence.

WHEREFORE, defendants Stryker Corporation, Stryker Sales Corporation, and Stryker Instruments respectfully request this Court:

(a) dismiss Plaintiff's Complaint and all claims with prejudice at the Plaintiff's cost;

(b) enter judgment in favor of Defendants;

(c) award Defendants their costs and attorneys' fees incurred in defending this action;

(d) award Defendants interest on the foregoing sums at the highest rate allowable by law;

(e) award all other relief to which Defendants appear entitled.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Defendants hereby demand trial by jury on all applicable issues of fact and damages in this litigation.

Respectfully submitted,

STRYKER CORPORATION, STRYKER SALES CORPORATION, and STRYKER INSTRUMENTS

/s/ Brian D. Fowler
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Attorney for Stryker Corporation, Stryker Sales Corporation, and Stryker Instruments

CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of January, 2009, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to:

Mary Lynn Tate
THE TATE LAW FIRM
110 Abingdon Place
Abingdon, Virginia 24211

and I hereby certify that I have mailed by United States Postal Service the document to the following non-CM/ECF participant:

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